07/812,886 12/20. MAK /0681.45001

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SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.
1805

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04/03/92

EXAMINER
1812

ART UNIT | PAPER NUMBER
04/03/
6

DATE MAILED

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined ☒ Responsive to communication filed on ELECTION 1/21/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-21 are pending in the application.
   Of the above, claims 4-10, 17-18 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 11-16, 19-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

PTO-326 (Rev.9-89) EXAMINER'S ACTION

Applicant's election with traverse of Group II, claims 1-3, 11-16, and 19-21 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that applicants do not believe that undue burden would be placed on the Exmainer to search Groups I and II in the same application. This is not found persuasive because burden has been demonstrated with the different classification and non-coextensive literature searches required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-10 and 17-18 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 5.

Claims 1, 3, and 11-15 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 3, and 11-15 of copending application Serial No. 07/538,372. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending application Serial No. 07/538,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because while they differ slightly in scope by their wording, they are claiming the same DNA sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new

and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-3, 11-16, and 19-21 are rejected under 35 U.S.C. § 101 because the claimed subject matter lacks patentable utility.

Claims 1-3 are drawn to DNA segments encoding all or a unique portion of GDF-1 protein or DNA fragments complementary to that DNA fragment. Although useful properties are alleged based upon the similarity of the GDF-1 amino acid sequence to the TGF-ß family, there is no evidence of record that this DNA sequence encodes a biologically useful protein possessing any particular properties. (See specification pages 10-11.) There is no utility alleged for the "unique portions" of the GDF-1 sequence although it is presumed that these may be considered DNA fragments based on their size as defined in the specification. Although the utility of the fragments is alleged to be their usefulness as probes for detecting the presence of respective complementary strands in nucleic acid samples, these have no utility except for further research (which is not a patentable utility) unless the GDF-1 sequence has utility. It is noted that DNA fragments unlike the "unique portions" do not appear to have a clear limitation as to length. It is deemed that small nucleotide sequences (less than about 15 nucleotides) would not be useful as probes even if the sequences are complementary. As such, for this subset of DNA fragments there is no utility

alleged. (See specification page 7.) The utility of the vectors and transformed host cells of claims 11-14 and the method of claim 15 turns on the utility of the sequences of claims 1-3.

Claim 16 is drawn to a DNA segment encoding a mammalian UOG-1 protein, or an epitope specific thereto, or a DNA fragment complementary to said DNA segment. There is no utility alleged for the UOG-1 DNA sequence other than it may be a receptor and may be involved with the biological activity for GDF-1. (See page 15, lines 9-29.) Likewise, DNA encoding epitopes or complementary DNA fragments would have no utility. The utility of the vectors and transformed host cells of claims 19-20 and the method of claim 21 turns on the utility of the sequences of claim 16.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 and 11-15 are rejected under 35 U.S.C. § 102(a) as being anticipated by Derynck et al. (U.S. Patent No. 4,886,747).

Derynck et al. teaches the amino acid and nucleotide sequences for mammalian TGFß1, TGFß2, and TGFß3. Vectors and transformed host cells are disclosed as well as a method of making the proteins recombinantly. (See abstract, claims, figures 1-5, Example 5.) It is noted that the TGFß1, TGFß2, and TGFß3 sequences have amino acids in common with the GDF-1 sequence of Figure 2 in the specification. There are nucleotides in common as well. Derynck et al. describes probes or mRNA sequences for that would have complementary nucleotides in common with the GDF-1 sequence of Figure 2 in the specification.

Claims 1-2 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Weeks et al.

Weeks et al. teaches the amino acid and DNA sequences for Vg-1 from Xenopus oocytes. Vectors are disclosed. (See abstract; Figures 1B and 2; Experimental Procedures, page 866.) It is noted that the Vg-1 sequence has amino acids in common with the GDF-1 sequence of Figure 2 in the specification. There are nucleotides in common as well.

Claims 1-3 and 11-15 are rejected under 35 U.S.C. § 102(e) as being anticipated by Wang et al. (U.S. Patent No. 5,013,649).

Wang et al. teaches the amino acid and DNA sequences for human BMP2A and BMP2B. Vectors and transformed host cells are

disclosed as well as a method of making the proteins recombinantly. (See abstract, claims, figures 1 and 2.) It is noted that the human BMP2A and BMP2B sequences have amino acids in common with the GDF-1 sequence of Figure 2 in the specification. There are nucleotides in common as well. Wang et al. describes probes that would have complementary nucleotides in common with the GDF-1 sequence of Figure 2 in the specification.

The specification defines GDF-1 to include any "unique portion" which is poorly defined in the specification. (See page 7.) It is unknown if the five or six amino acids or 15 or 18 nucleotides must be contiguous, as in a sequence, or must merely be present in the sequence. When "unique portion" is recited in the claims, it is unknown if the 15 or 18 nucleotides of the GDF-1 sequence must be present or if any nucleotide sequence encoding the five or six amino acids must be present. As such Wang et al., Derynck et al., and Weeks et al. are deemed to be anticipatory references for the invention as claimed.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written

description and enabling disclosure.

Applicant has failed to disclose how to use the claimed invention. Useful properties for GDF-1 are alleged based upon the similarity of the amino acid sequence encoded to the TGF-ß family; however, there is no evidence of record that this DNA sequence encodes a biologically useful protein possessing any particular properties and in the absence of such a showing it is unknown how to use this DNA sequence. The use of the DNA fragments is alleged to be their usefulness as probes for detecting the presence of respective complementary strands in nucleic acid samples, these have no use except for further research (which is not a patentable use) unless the GDF-1 sequence has a use. It is noted that DNA fragments do not appear to have a clear limitation as to length. It is deemed that small nucleotide sequences (less than about 15 nucleotides) would not be useful as probes even if the sequences are complementary. As such, for this subset of DNA fragments it is unknown how to use them.

There is no description of how to use the DNA sequence encoding UOG-1, the vectors, host cells, or method of producing associated with this UOG-1 encoding sequence. There is no description of epitopes or fragments of UOG-1 as useful for probes or otherwise.

The metes and bounds of the DNA sequences of claims 1-3 and 16 are unknown. The multitude of sequences encompassed by these

claims are not described nor enabled. It is unknown how to determine what sequences a fragment or epitope encompasses. It would constitute undue experimentation to determine all such sequences that are encompassed by these claims. There is no description nor enablement for identifying epitopes of either GDF-1 or UOG-1.

It is unclear from the specification whether the method of production as set forth in claim 15 has actually been performed or whether this is a prophetic disclosure. The method is deemed to be unenabled for fragments encoding small peptides. While expression of GDF-1 is described on page 6 in the description of figure 9, insufficient details are presented to determine what was performed. It does not appear that the protein was isolated as set forth in the method. There does not appear to be a further discussion of figure 9 in the specification.

The method of claim 21 is clearly prophetic. There is no description of producing vectors, transformed host cells, or producing the protein encoded by the DNA sequence recombinantly.

Claims 1-3, 11-16, and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 2, 11, 15, and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

Claim 2 is indefinite for failing to indicate whether the DNA sequence encoding the GDF-1 protein is intended to be claimed (i.e. the coding region) or any portion of the sequence of Figure 2, 11A, or 11B. It is noted that the sequence of figures 11A and 11B include the sequences for UOG-1. Due to the "fragment" language of claim 1, this claim reads on DNA sequences for both GDF-1 and UOG-1 and not GDF-1 alone. As such, it is unclear whether this claim improperly broadens the scope of claim 1 as claim 1 is limited to DNA sequences that encode GDF-1.

Claims 11 and 19 are indefinite for failing to indicate that the DNA segment of claim 1 and the vector are operably linked or in some manner connected. As the claim stands, the vector does not have to contain the DNA segment of claim 1 which appears to be applicant's intent.

Claim 15 is indefinite in reciting "segment". There is no clear antecedent basis for this term in the preamble of the claim or claim 12 although there appears to be antecedent basis in claim 11 upon which claim 12 depends. Clarification is requested.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l). Correction of the following is required: Vectors containing DNA sequences encoding UOG-1 and transformed host cells containing these vectors do not

appear to be present in the specification. The methods of claims 15 and 21 as written do not appear to be present in the specification. Applicant is requested to point out the basis in the specification for these claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Beltz et al. discloses isolation of multigene families and determination of homologies by filter hybridization techniques. Cross-hybridization techniques and techniques to discriminate related genes are disclosed.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne Porta Allen whose telephone number is (703) 308-0666.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID L. LACEY
SUPERVISORY PATENT EXAMINER
GROUP 180
4/3/92